

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 146-232 are pending in the application, with claims 146-148, 176-177, and 204-206 being the independent claims. New claims 204-232 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. The Amendments

New claims 204-232 are directed to methods of treating, alleviating or reducing one or more symptoms of allergic disease by administering a kiwifruit extract from *Actinidia arguta*, *Actinidia polygama* or *Actinidia kolomikta* to a mammal in need thereof in an amount sufficient to treat, alleviate or reduce one or more symptoms of allergic disease. The methods of the present invention are also directed to the *in vivo* effects of hardy kiwifruit extract administration (*i.e.* modulating IgE, IgG1, IgG2a, Th1 cytokine, and Th2 cytokine serum levels).

Support for the new claims can be found *inter alia* in the disclosure as follows:

CLAIM	SUPPORT
205	See, for example, Example 2.
207	See, for example, page 5, line 23-27; page 6, lines 5-7; and page 6, lines 27-29.
208, 216	See, for example, page 6, lines 31-32.

CLAIM	SUPPORT
200, 210	See, for example, page 5, lines 18-21.
212	See, for example, page 6, lines 34-37; and page 7, line 1.
213	See, for example, page 13, line 5.
214	See, for example, page 8, lines 34-36.
204, 206, 215	See, for example, page 10, lines 1-9.
216-224	See, for example, Experimental Example 7.
225	See, for example, page 7, lines 20-32; and Example 1.
226	See, for example, page 9, lines 1-3.
227-231	See, for example, page 9, lines 27-31.
232	See, for example, page 9, lines 9-10; page 10, lines 26-29; page 12, lines 3-4; and page 12, lines 19-25.

Accordingly, no new matter is believed to have been added by the amendments, and their entry is respectfully requested.

III. The Rejections

A. Rejections Under 35 U.S.C. § 112

Claims 38, 40-72, and 110-145 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In Applicants' reply dated April 10, 2008, Applicants had canceled claims 38, 40-72, and 110-145 solely in an effort to expedite prosecution, and without acquiescing to the propriety of the rejection. As the rejection may be applied to new claims 204-233, Applicants assert that the new claims 204-232 do not recite "reduce the risk [of allergic disease or non-allergic inflammatory disease in a mammal]." As such, the rejection is moot with regard to new claims 204-232.

B. Rejections Under 35 U.S.C. § 103

Claims 38, 40-59, 62, 65-67, and 110-112 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Murad (U.S. Pat. No. 6,630,163) in view of Endres *et al.* (German Pat. Appl. No. DE 19758090 A1, Abstract). Applicants respectfully traverse the rejection.

Applicants previously addressed the rejection of claims 38, 40-59, 62, 65-67, and 110-112 in the Amendment and Reply filed on April 10, 2008. In so far as the rejection may apply to new claims 204-232, Applicants provide the following comments. Applicants reiterate the assertions made in Applicants' reply dated April 10, 2008. Specifically, Murad merely mentions the use of fruit extracts generally to treat a multitude of inflammatory skin diseases, and mentions kiwi in a laundry list of fruits. Murad does not disclose treatment of allergic disease with a hardy kiwifruit extract from *Actinidia arguta*, *Actinidia polygama* or *Actinidia kolomikta*. Murad contains only one working example in which fruit is used for any therapeutic or preventive purpose: treating sun-exposed skin. Murad provides a laundry list of inflammatory dermatoses that are contemplated for treatment, however, there is no working example showing that the Murad compositions were ever used to treat such conditions, and Murad provides no specific teaching that would guide one of ordinary skill in the art on how the compositions would be used for such purposes. Moreover, Murad does not discuss IgE, IgG1, IgG2a, Th1 cytokine, or Th2 cytokine serum levels. As such, the reference does not teach all of the claim limitations of the new claims presented hereto.

While Endres mentions using *Actinidia arguta* extracts to treat inflammatory dermatological conditions, Endres does not disclose treatment of **allergic disease** with

extracts of kiwifruit from *Actindia arguta*, *Actinida polygama* or *Actinida kolomikta*.

Therefore, there is no suggestion or motivation to treat allergic disease in a mammal in need thereof with kiwifruit extracts of the claimed invention, simply by combining the Murad and Endres references. Additionally, the combined references fail to provide a reasonable expectation for successfully treating allergic disease by administering a kiwifruit extract to a mammal in need thereof. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection.

The Examiner has also rejected claims 38, 40-59, 62, 65-67, and 110-112 under 35 U.S.C. § 103(a) as allegedly unpatentable over Murad (U.S. Pat. No. 6,630,163) in view of Udagawa (Japanese Pat. Appl. No. JP 61140510 A, Abstract). Applicants respectfully traverse the rejection. In so far as the rejection may apply to the new claims 204-232, Applicants provide the following comments.

Udagawa mentions the use of *Actinidia kolomikta* and *Actinidia polygama* fruit extracts in cosmetics but does not disclose the use of kiwifruit extracts generally or extracts of the species *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* in pharmaceutical compositions. This reference also does not discuss serum IgE, IgG1, IgG2, Th1 cytokine, or Th2 cytokine levels. As such, Udagawa does not teach addressing the mechanism underlying allergic disease or administering kiwifruit extracts to pharmaceutically treat any condition of a mammal in need thereof, let alone the ***allergic conditions*** of the present invention.

For the reasons provided above, Applicants assert that there is no suggestion or motivation to treat allergic disease with the claimed extracts of kiwifruit from *Actinidia arguta*, *Actinidia polygama* or *Actinidia kolomikta* simply by combining the Murad and

Udagawa references. Additionally, the combined references fail to provide a reasonable expectation for successfully treating allergic disease by administering a kiwifruit extract to a mammal in need thereof. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection.

The Examiner has also rejected claims 38, 40-64, 69-72, 110-135, and 142-145 under 35 U.S.C. § 103(a) as allegedly unpatentable over Forastiere *et al. Thorax* 55:283-288 (2000) in view of Endres and/or Udagawa. Applicants respectfully traverse the rejection. In so far as the rejection may apply to the new claims 204-232, Applicants provide the following comments.

Forastiere discusses treating asthma symptoms by administering common kiwifruit. This reference does not disclose administering any specific type of kiwifruit extract, let alone the kiwifruit extracts from *Actinidia arguta*, *Actinidia polygama* and *Actinidia kolomikta*. Nor does this reference teach alleviating the symptoms of anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, contagious dermatitis, urticaria, insect allergy, food allergy or drug allergy by administering kiwifruit extracts. Thus, Forastiere fails to teach each and every limitation of the pending claims.

Applicants respectfully assert that there is no suggestion or motivation to combine the Forastiere and Udagawa references, either within the references themselves or within the knowledge of one of ordinary skill in the art. Even if the references are combined, the references fail to provide a reasonable expectation for successfully treating the claimed allergic conditions with an extract of kiwifruit from *Actinidia arguta*, *Actinidia polygama* or *Actinidia kolomikta* to a mammal in need thereof, as the

references discuss diverging uses for their compositions. The therapeutic use of the Forastiere kiwifruit differs substantially from the cosmetic use of the Udagawa kiwifruit extracts.

Applicants also respectfully assert that there is no suggestion or motivation to combine the Forastiere and Endres references either within the references themselves or within the knowledge of one of ordinary skill in the art. Even assuming, *arguendo*, that the cited art was combined, the claimed invention would not be obtained as neither Forastiere nor Endres teaches treating ***allergic conditions*** with a ***an extract of kiwifruit from Actinidia arguta, Actinidia polygama or Actinidia kolomikta*** to a mammal in need thereof, where the allergic disease is anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, asthma, contagious dermatitis, urticaria, insect allergy, food allergy or drug allergy. Endres does not fill any of the deficits that exist in Forastiere: (1) providing a kiwifruit and not an extract or (2) treating the above-outlined allergic conditions.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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